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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,776	06/21/2002	Kci Tashiro	29288.5600	2614

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EXAMINER

HAQ, SHAFIQUK

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/089,776	Applicant(s) TASHIRO ET AL.	
	Examiner Shafiqul Haq	Art Unit 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/29/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicants' responses and amendments filed August 26, 2005 is acknowledged and entered.
2. Claim 8 has been cancelled.
3. Claims 1-7 and 9-16 are pending and under active prosecution.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-7 and 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. In formula (II) of claims 1 and 16, "R" is bonded to either sides i.e. not depicted as a terminal group. However, to form a covalent bond with a protein, the functional group "R" needs to be a terminal group. Therefore, its not clear how "R" not being a terminal group, can react with a protein to form a covalent linkage.
4. Claims 1-7 and 9-15 are indefinite and confusing. Although claim 1 uses method language such as "forming a composite" and "steps (a) to (c)", "(a)" through "(c)" appear to describe components of a composition. For a "method of detecting", it would appear that steps "(a)" -"(c)" should be written as method steps. For example "binding a first antibody to a solid phase" followed by "adding the sample containing cytokine" followed by "binding the second antibody to the cytokine", etc.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-16 are again rejected under 35 U.S.C. 103(a) as being unpatentable over each of 1) Yuan et al (Anal. Chem. 1998, Vol. 70, No.3, pp. 596-601) or Matsumoto et al (US 5,859,297) and in view of 2) Pennanen et al (Int. J. Immunopharmacol. 1995, Vol. 17, No. 6, pp. 475-480) for the reasons set forth in paragraph 9 of the 7/2/05 office action.

***Response to Argument***

7. Applicant's arguments filed 8/26/05 have been fully considered, but are not persuasive to overcome the rejections under 35 USC 112 and 35 USC 103.
8. Applicant's amendment regarding function group "R" clarifies problem with formula (I), but not with formula (II) of claims 1 and 16 and thus suffers from indefiniteness for the same reason of record of page 2 of last office action. With regard to method steps of claim 1, the claim is still indefinite and confusing as discussed above in paragraph 4 of this office action.
9. In response to applicant's argument that "to anticipate a claim, the cited reference must teach each of the element of the rejected claims", the examiner would like to clarify that the 35 U.S.C. §103 rejection is base on obviousness, not on anticipation and obviousness can only be established by combining or modifying the teachings of

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the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fines*, 837 F.2d 1071, 5USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In this case, Yaun et al. discloses that use of  $\beta$ -diketone ligand (BHHCT) gave remarkable superiority over conventional organic fluorescent labels and other lanthanide labels in time resolved fluorometric determination of AFP as the detection limits are greatly improved (page 597) and Matsumoto et al. also disclose that the use of SA-BHHCT-Eu<sup>3+</sup> in a time-resolved immunoassay, remarkably improved the detection limit of AFP (from 1ng/ml to 10<sup>-6</sup>ng/ml; column 24, lines 15-25). Therefore, motivation is there to incorporate the  $\beta$ -diketone fluorescent structure portion (BHHCT) for detection of proteins by time-resolved immunoassay. Pannanen et al, as discussed in paragraph 9 of last office action, disclose detection of cytokine (see page 478) by time resolved immunoassay with the only difference being that they do not disclose fluorescent structure portion (BHHCT). Although, Pennanen's disclosure is directed to screening drug effects on cytokine secretion, detection or measuring fluorescence is encompassed in the screening method (page 478).

Therefore, while  $\beta$ -diketone fluorescent structure portion (BHHCT) is known in the art to greatly improve fluorescent detection (Yaun and Matsumoto) in time-resolved immunoassay, one skilled in the art would obviously be motivated to include cytokine of Pennanen as an equivalent analyte in the method of Yaun et al

or Matsumoto et al. utilizing BHHCT, with the expectation of detecting/measuring of cytokine with a high sensitivity in a sample. Therefore, the 35 USC 103 (a) rejection is still deemed to be appropriate.

With regard to incorporation of "chemokine" in claims 1 and 16, Pennanen et al. refer to cytokines and other cytokines (page 479, line 5 of 1<sup>st</sup> paragraph, right column) and do not exclude chemokines (i.e. chemotactic cytokines).

While applicants state that the Leonard article establishes that chemokines are present in very low levels in biological fluids, applicants have not set forth any reasoning as to why chemokines would not be expected to be equivalent analytes as established by the examiner i.e. there appears to be no reason to expect that a chemokine would not bind with its corresponding antibody on a solid support. Furthermore, Leonard article is directed to the detection of chemokine autoantibody and thus is not relevant since chemokine (not antibody) is detected in claimed method.

### ***Conclusion***

**10. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

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any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

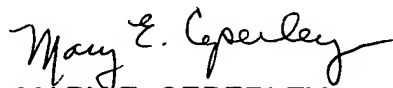
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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